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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,122	05/30/2001	Paul Patrick Cleary	600.450US2	7859

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EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT PAPER NUMBER

1645

DATE MAILED: 11/12/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/870,122

Applicant(s)

Cleary et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on May 2, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-98 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Restriction/Election

- 1) Claims 1-98 are under prosecution. Claims 34 and 37 are product claims improperly dependent from method claims. Claims 58 and 59 are method claims improperly dependent from a product claim. These claims have not been included in the restriction requirement set forth below.
- 2) **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
- 3) Restriction to one of the following inventions is required under 35 U.S.C. 121:
 1. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPA49D130A, and a vaccine comprising the same, classified in class 530, subclass 350.
 2. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPA49H193A, and a vaccine comprising the same, classified in class 530, subclass 350.
 3. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPA49N295A, and a vaccine comprising the same, classified in class 530, subclass 350.
 4. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPA49S512A, and a vaccine comprising the same, classified in class 530, subclass 350.
 5. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, Δ SCPA49, and a vaccine comprising the same, classified in class 530, subclass 350.
 6. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPA1D130A, and a vaccine comprising the same, classified in class 530, subclass 350.
 7. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPA1H192A, and a vaccine comprising the same, classified in class 530, subclass 350.

8. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPA1N295A, and a vaccine comprising the same, classified in class 530, subclass 350.
9. Claims 13, 14, 73 and 74, drawn to a streptococcal C5a peptide variant, SCPA1S512A, and a vaccine comprising the same, classified in class 530, subclass 350.
10. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPBD130A, and a vaccine comprising the same, classified in class 530, subclass 350.
11. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPBH193A, and a vaccine comprising the same, classified in class 530, subclass 350.
12. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPBN295A, and a vaccine comprising the same, classified in class 530, subclass 350.
13. Claims 13 and 73, drawn to a streptococcal C5a peptide variant, SCPBS512A, and a vaccine comprising the same, classified in class 530, subclass 350.
14. Claims 7, 8, 70 and 71, drawn to a streptococcal C5a peptide variant having a modification/ substitution at amino acid residue 260, 261, 262, 415, 417, 130, 193, 295 or 512, classified in class 530, subclass 350.
15. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a, SCPA49D130A, classified in class 424, subclass 244.1.
16. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a, SCPA49H193A, classified in class 424, subclass 244.1.
17. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a, SCPA49N295A, classified in class 424, subclass 244.1.
18. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a, SCPA49S512A, classified in class 424, subclass 244.1.
19. Claim 42, drawn to a method of protecting a mammal against streptococcal

- infection by administering a vaccine comprising the streptococcal C5a, Δ SCPA49, classified in class 424, subclass 244.1.
20. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPA1D130A, classified in class 424, subclass 244.1.
 21. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPA1D130A, classified in class 424, subclass 244.1.
 22. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPA1H192A, classified in class 424, subclass 244.1.
 23. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPA1N295A, classified in class 424, subclass 244.1.
 24. Claims 42 and 43, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPA1S512A, classified in class 424, subclass 244.1.
 25. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPBD130A, classified in class 424, subclass 244.1.
 26. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPBH193A, classified in class 424, subclass 244.1.
 27. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPBN295A, classified in class 424, subclass 244.1.
 28. Claim 42, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant, SCPBS512A, classified in class 424, subclass 244.1.

29. Claims 39 and 40, drawn to a method of protecting a mammal against streptococcal infection by administering a vaccine comprising the streptococcal C5a variant with a modification/ substitution at 260, 261, 262, 415, 417, 130, 193, 295 or 512, classified in class 424, subclass 244.1.
30. Claims 89 and 90, drawn to a polynucleotide encoding an SCP variant comprising a modification/ substitution at 260, 261, 262, 415, 417, 130, 193, 295 or 512, classified in class 424, subclass 184.1.
31. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPA49D130A, classified in class 536, subclass 23.7.
32. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPA49H193A, classified in class 536, subclass 23.7.
33. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPA49N295A, classified in class 536, subclass 23.7.
34. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPA49S512A, classified in class 536, subclass 23.7.
35. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, Δ SCPA49, classified in class 536, subclass 23.7.
36. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPA1D130A, classified in class 536, subclass 23.7.
37. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPA1H192A, classified in class 536, subclass 23.7.
38. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPA1N295A, classified in class 536, subclass 23.7.
39. Claims 92 and 93, drawn to a polynucleotide encoding streptococcal C5a variant, SCPA1S512A, classified in class 536, subclass 23.7.
40. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPBD130A, classified in class 536, subclass 23.7.
41. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant,

SCPBH193A, classified in class 536, subclass 23.7.

42. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPBN295A, classified in class 536, subclass 23.7.

43. Claim 92, drawn to a polynucleotide encoding streptococcal C5a variant, SCPBS512A, classified in class 536, subclass 23.7.

Claims 1-6, 10-12, 15-27, 60-69 and 75-78 are considered as linking claims and would be joined with one of inventions 1 through 14, if elected.

If invention 14 is elected, then Applicants should elect a variant with one of the amino acid substitutions. Claims 9 and 72 are linking claims and would be joined with one of these inventions, if elected.

Claims 28-33, 35, 36, 38 and 44-57 are considered as linking claims and would be joined with one of inventions 15-28, if elected.

If invention 29 is elected, then Applicants should elect a variant with one of the amino acid substitutions. Claim 41 is a linking claim and would be joined with one of these inventions, if elected.

If invention 30 is elected, then Applicants should elect a variant with one of the amino acid substitutions. Claim 91 is a linking claim and would be joined with one of these inventions, if elected.

Claims 79-88 and 94-98 are considered as linking claims and would be joined with one of inventions 30 through 43, if elected.

4) Inventions 1-43 are distinct from one another. Inventions 30-43 are drawn to individual polynucleotides, whereas inventions 1-14 are drawn to different SCP peptidase variants. The two products are structurally and functionally distinct from each other and belong to two different classes. Inventions 15-29 are drawn to methods of using the various SCP variants. Although many of these inventions belong to the same class/subclass, the products encompassed in these inventions are structurally and therefore, functionally or biologically distinct from one another, each sequence requiring a separate search.

5) Inventions 1 and 15; inventions 2 and 16; inventions 3 and 17; inventions 4 and 18; inventions 5 and 19; inventions 6 and 20; inventions 6 and 21; inventions 7 and 22; inventions 8

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and 23; inventions 9 and 24; inventions 10 and 25; inventions 11 and 26; inventions 12 and 27; inventions 13 and 28; and inventions 14 and 29 are related as product and process of using the product. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process of using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P 806.05(h)). In the instant case, the peptidase variants of inventions 1-14 can be used in a materially different process, for example, as a coating antigen in an *in vitro* diagnostic assay.

6) Inventions 30-43 are independent and distinct inventions. The polynucleotides of inventions 30-43 are not required to make the protein products of inventions 1-14, because the latter can be synthesized chemically.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classifications/subclassifications and divergent subject matter, restriction for examination purposes as indicated is proper.

7) Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R 1.143).

8) Applicants are reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filled petition under C.F.R 1.48(b) and by the fee required under 37 C.F.R 1.17(h).

9) Any inquiry concerning this communication or earlier communication(s) from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail service. The Examiner can normally be reached on Monday to Friday from 7.15 a.m to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's

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supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October, 2002


S. DEVI, PH.D.
PRIMARY EXAMINER